

SUMMARY OF SAFETY AND EFFECTIVENESS

September 20, 2002

Trade Name: AutoMed 3200 infusion pump

Common Name: Infusion Pump

Classification Name: Pump, Infusion,

Classification Panel: General Hospital and Personal Use Device

All questions and/or comments concerning this document should be made to:

Robert J. Bard, Esq.
Managing Director

HELP Technologies
24312 Armada Dr.
Dana Point, CA 92629
Telephone: 949.235.0545
Fax: 949.240.3460

1.0 DEVICE DESCRIPTIONS

The AutoMed 3200 infusion pump with integrated administration set and drug reservoir is a rotary peristaltic pump. Associated dedicated administration set, AM 330, and accessories are part of the overall system. The system is suitable for use as an ambulatory device and is intended for use in the hospital, home environment or alternative care sites.

2.0 INTENDED USE

For general infusion use. Routes of infusion include intravenous, percutaneous, subcutaneous, inter-arterial and epidural and into the intra-operative (soft tissue / body cavity) site.

The *AutoMed* 3200 infusion pump is intended for patient-controlled infusion using the integrated bolus button.

General infusion use includes continuous infusion of a local anesthetic near a nerve for regional anesthesia and pain management for pre-operative, perioperative and postoperative surgery.

3.0 PREDICATE PRODUCTS

The AutoMed 3200 is substantially similar to the following devices: McKinley WalkMed® 300, 350, PCA and IC; Sorenson Medical, Inc, MicroJect® Model 30 pump, Model 200 Pump, Model PCA Pump, Model PCEA Pump; Stryker Instruments Pain Pump II; and the I-Flow PainBuster Infusion Kit.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 27 2003

Mr. Robert J. Bard
Managing Director
HELP Technologies
24312 Armada Drive
Dana Point, California 92629

Re: K023973

Trade/Device Name: AutoMed 3200 Infusion Pump
Regulation Number: 880.5725, 880.5440
Regulation Name: Infusion Pump, Intravascular Administration Set
Regulatory Class: II
Product Code: FRN, FPA
Dated: September 20, 2002
Received: December 2, 2002

Dear Mr. Bard:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration

Page 2 – Mr. Bard

and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Susan Runner". The signature is fluid and cursive, with the first name "Susan" being more prominent than the last name "Runner".

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K 023973

Device Name: AutoMed 3200 infusion pump

Indications for Use:

The *AutoMed* 3200 ambulatory infusion pump with integrated administration set is intended for general infusion use. Routes of infusion include intravenous, percutaneous, subcutaneous, inter-arterial and epidural, and into intra-operative (soft tissue / body cavity) sites. The *AutoMed* 3200 infusion pump is also intended for patient-controlled infusion using the integrated bolus button. General infusion uses include continuous infusion of a local anesthetic near a nerve for regional anesthesia and pain management for pre-operative, perioperative and postoperative surgery.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUED ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

Von N. H. M. M. For PXC
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

(Optional Format 1-2-96)

510(k) Number: K023973